

# LEGAL HIGH? THE HIGH STAKES REGULATORY QUESTIONS ABOUT DELTA-8 THC & OTHER EMERGING PSYCHOACTIVE CANNABINOIDS

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## ABSTRACT

The 2018 Farm Bill legalized hemp federally, thus marking a dramatic change in federal policy regarding cannabis. The legalization of hemp has led to the rapid proliferation of an intoxicating hemp-derived substance called Delta-8 THC in various products at gas stations, corner markets, and smoke shops across the United States. Delta-8 is only slightly chemically different from Delta-9 THC which is unambiguously illegal under federal law and is the better-known compound in cannabis that gets a user “high.” A regulatory gap has developed where the federal government regulates Delta-9 THC but not the various other compounds in the cannabis plant that have entered the market. This note argues that Congress must act to mandate and empower the Federal Drug Administration to regulate Delta-8 and other cannabinoids, not to ban them, but to facilitate their safe and responsible usage.

## INTRODUCTION

As it does every five years, Congress passed the Agriculture Improvement Act of 2018, also known as the “2018 Farm Bill,” which sets national agriculture, nutrition, conservation, and forestry policy.<sup>1</sup> The 2018 Farm Bill marked a dramatic change in federal policy regarding the plant

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1. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

*Cannabis sativa L.*, commonly referred to as “cannabis.”<sup>2</sup> The Bill legalized hemp federally.<sup>3</sup> The legalization of hemp has led to the rapid proliferation of an intoxicating substance called Delta-8 THC in gas stations, corner markets, and smoke shops across the United States since 2020, in products ranging from infused gummies to pre-rolls.<sup>4</sup>

By legalizing hemp, the 2018 Farm Bill created two classes of cannabis. The first class is called “hemp” and it includes all strains of cannabis that contain 0.3% or less delta-9 tetrahydrocannabinol (“Delta-9 THC”) concentration. The other class of cannabis, which can be understood as federally illegal “marijuana,” includes all strains of the cannabis plant that contain greater than 0.3% Delta-9 THC concentration.<sup>5</sup> The class of cannabis defined as “hemp” was made legal because of provisions in the 2018 Farm Bill, while the class defined as “marijuana” remained federally illegal.<sup>6</sup>

Delta-9 THC, commonly referred to as just “THC,” is the compound that gets a user “high” when consuming cannabis.<sup>7</sup> Delta-8 tetrahydrocannabinol, commonly referred to as “Delta-8” or “Delta-8

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2. Anna Stasilowicz et al., *Cannabis sativa L. as a Natural Drug Meeting the Criteria of a Multitarget Approach to Treatment*, 22 INT J. MOLECULAR SCI. 778 (2021). This note will use the term “cannabis” as an umbrella term that encompasses any plant or substances derived from any plant belonging to the genus *Cannabis*. Both “marijuana” and “hemp” fall under this term in this note. This note will cite materials that inconsistently use the terms like “marijuana,” “hemp,” and “marihuana” that do not align with scientific understanding of the plant. There is thought to be multiple species of the genus *Cannabis* “includ[ing] up to three species, each with a very long history of domestication.” Antonino Pollio, *The Name of Cannabis: A Short Guide for Nonbotanists*, 1 CANNABIS & CANNABINOID RSCH. 234, (Oct. 1, 2016). *Cannabis sativa L.* is one of those species of genus *Cannabis*. *Id.* However, the distinctions between the species of genus *Cannabis* are up for debate. Debate continues in the scientific community on how to classify cannabis varieties. “[T]o paraphrase and expropriate an old Yiddish expression: 12 botanical taxonomists, 25 different opinions . . . Some espouse Cannabis as a single species, while others describe up to four: *Cannabis sativa*, *Cannabis indica*, *Cannabis ruderalis*, and *Cannabis afghanica* (or *kafiristanica*).” Daniele Piomelli & Ethan B. Russo, *The Cannabis sativa Versus Cannabis indica Debate: An Interview with Ethan Russo, MD*. 1 CANNABIS & CANNABINOID RSCH. 44 (Jan. 1, 2016).

3. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

4. Dario Sabaghi, *Study: How Popular is Delta-8 THC In The United States?*, FORBES (Jan. 12, 2022), <https://www.forbes.com/sites/dariosabaghi/2022/01/12/study-how-popular-is-delta-8-thc-in-the-united-states/?sh=48b857dc4cfc> [https://perma.cc/7397-TUR2].

5. *Id.*

6. *Id.*

7. *5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc> (last visited Jan 30, 2022) [hereinafter *FDA 5 Things to Know*] [https://perma.cc/7QU5-QQDE].

THC,” is a cannabis compound that is like Delta-9 THC and has similar effects if consumed.<sup>8</sup> The 2018 Farm Bill legalized all cannabis that contains a Delta-9 THC concentration of 0.3% or less, so Delta-9 THC became the regulated banned compound in the U.S. Drug Enforcement Agency’s regulation of cannabis, not the entire plant as it has been in the past. Thus, all other compounds in the cannabis plant like Delta-8 THC became federally legal because those compounds are not Delta-9 THC. A regulatory gap has developed, where the federal government is not using its authority to regulate all other compounds in the cannabis plant like CBD and Delta-8 THC that have entered the market.

Congress must act to mandate and empower the Federal Drug Administration to regulate Delta-8. The FDA has the capability to create and enforce a comprehensive regulatory scheme for Delta-8 and other cannabinoids. There is not currently any evidence that Delta-8 is harmful when used properly, however, people can get sick from improperly consuming the compound, especially children.<sup>9</sup> The FDA can help protect consumers as well as the cannabinoid and hemp industries by implementing and enforcing health and safety regulations on cannabinoids which currently exist in a regulatory gap.

Part I of this note examines the history of cannabis regulation in the United States and the current legal status of Delta-8 at the federal and state levels. Part II analyzes public policy issues relating to the current legal status of Delta-8 and why Congress must act to address the problems that it created when it passed the 2018 Farm Bill. Finally, Part III proposes actions that Congress should take to adjust federal regulations so that they acknowledge the cannabis market more holistically. It should do so—not with the intent to ban all cannabis again, but to protect the public’s ability to safely enjoy the benefits that cannabis can offer while still allowing progress to be made in the development of the industry.

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8. *Id.*

9. Dana G. Smith, *How Delta-8 THC Works, and Why Experts Are Worried About It*, N.Y. TIMES (July 25, 2022), <https://www.nytimes.com/2022/07/01/well/mind/delta-8-thc-marijuana.html> [<https://perma.cc/RT9M-3F4A>].

## I. HISTORY

### *A. The Path to Federal Prohibition of Cannabis*

The current legal status of cannabis is rooted in the Pure Food and Drug Act which was passed by Congress in 1906.<sup>10</sup> The legislation required that “patent drugs” sold to the public accurately label their contents.<sup>11</sup> At the time, so called “patent drugs” were widely available.<sup>12</sup> These drugs were often marketed as cure-all miracle medicines that contained secret special ingredients. However, often these patent medicines contained ingredients like narcotics or cannabis without informing the consumer of such.<sup>13</sup> Understandably, the nondisclosure of these ingredients in these widely available, utilized, and prescribed patent drugs was a public health issue, so Congress passed the Pure Food and Drug Act.<sup>14</sup> The legislation did not outlaw cannabis.<sup>15</sup> Instead, the statute was designed to require that companies inform the public when patent drugs or other manufactured products offered for sale to the public contained cannabis.<sup>16</sup>

While the Pure Food and Drug Act was the first federal restriction on the sale of cannabis, states found themselves wanting to further discourage the consumption of cannabis within their borders.<sup>17</sup> As a result, several states passed laws making cannabis illegal.<sup>18</sup> These laws often accompanied alcohol prohibition laws that were passed as a part of the temperance movement at the turn of the twentieth century.<sup>19</sup> The conflicting state and federal regulatory scheme that developed during this period foreshadowed the contemporary complex state and locality patchwork of cannabis product legality that interplays with sometimes contradictory federal law.

In response to the state government and general public’s continued concern about largely unregulated cannabis and other drugs, the federal

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10. Pure Food and Drug Act, 59 Pub. L. No. 59-384, 34 Stat. 768 (1906).

11. DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* 2 (3d ed. 1999).

12. *Id.* at 3.

13. *Id.* at 22.

14. *Id.* at 22.

15. *Id.* at 218.

16. *Id.*

17. ROBERT F. WALTON, *MARIJUANA, AMERICA'S NEW DRUG PROBLEM* 37 (1938).

18. *Id.*

19. *Id.*

government stepped back in to further regulate cannabis by replacing the 1906 Pure Food and Drug Act with the Pure Food, Drug, and Cosmetics Act of 1938.<sup>20</sup> The legislation established the Food and Drug Administration and its regulatory power over food and drugs.<sup>21</sup> The legislation named both “marihuana” and “cannabis” separately as dangerous habit forming drugs.<sup>22</sup> Any drug that was deemed misbranded under the Pure Food, Drug, and Cosmetics Act was subject to seizure and destruction by the FDA if it contained cannabis

or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, quantity, and percentage of such substance or derivative and in juxtaposition therewith the statement ‘Warning-May be habit forming[.]’<sup>23</sup>

Cannabis was by no means banned by the Pure Food, Drug, and Cosmetics Act, but passage of the legislation marked the next step toward federal cannabis prohibition. However, it is notable that Congress in 1938 appeared to understand that there were “chemical derivative[s]” of cannabis that had properties that presumably differed.<sup>24</sup> Congress appears to note that some derivatives of cannabis are dangerous and habit-forming while others may not be.<sup>25</sup> In the intermediary statutory regulation framework prior to cannabis prohibition, Congress was regulating only the “habit forming” elements that may exist within cannabis.<sup>26</sup>

Around the same time as the passage of the Pure Food, Drug, and Cosmetics Act, Congress took another significant step towards prohibition

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20. Pure Food, Drug, and Cosmetics Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040.

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.* According to contemporary studies, marijuana is habit forming and around 30% of users are classified as having “Marijuana Use Disorder”. Deborah S. Hasin et al., *Prevalence of Marijuana Use Disorders in the United States Between 2001-2002 and 2012-2013*, 72 JAMA PSYCHIATRY 1235 (Dec. 2015), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2464591> [<https://perma.cc/6SZF-TYP7>].

of cannabis by passing the Marihuana Tax Act of 1937.<sup>27</sup> It placed significant taxes on marijuana, which effectively “restrict[ed] possession of the drug to individuals who paid an excise tax for certain authorized medical and industrial uses.”<sup>28</sup> Certain people and businesses were permitted to register with the government and pay a special tax before selling, importing, manufacturing, prescribing, or transferring marijuana legally.<sup>29</sup> It also created an elaborate paperwork system to track cannabis throughout the stream of commerce.<sup>30</sup> In order to transfer marijuana, one needed to acquire a special government order form obtained by the transferee.<sup>31</sup> To obtain the order form, the transferee was required to pay a special tax of either \$1 per ounce if the transferee had already registered or \$100 per ounce if the transferee had not already registered.<sup>32</sup> If a transfer was made without the transfer form and the transferee did not pay the special tax, the transferor was responsible for paying the tax.<sup>33</sup> Failure to comply with this tax system was a federal crime.<sup>34</sup>

Additionally, the Marihuana Tax Act defined cannabis in a way that considered the differences between the different parts of the cannabis plant:

The term ‘marihuana’ means all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin; but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the

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27. Marihuana Tax Act of 1937, Pub. L. No. 75–238, 50 Stat. 551 (repealed 1971).

28. *Id.*; *Marijuana Timeline*, PBS FRONTLINE, <https://www.pbs.org/wgbh/pages/frontline/shows/dope/etc/cron.html> (last visited Jan 30, 2022) [<https://perma.cc/6MYG-GRFU>].

29. Marihuana Tax Act of 1937, Pub. L. No. 75–238, 50 Stat. 551 (repealed 1971).

30. *Id.*

31. *Id.*

32. *Id.*; Accounting for inflation \$1.00 in 1937 is worth around \$19.62 today and \$100 in 1937 is worth around \$1,961.62. *CPI Inflation Calculator*, U.S. BUREAU OF LAB. STAT., [https://www.bls.gov/data/inflation\\_calculator.htm](https://www.bls.gov/data/inflation_calculator.htm) (last visited Jan 30, 2022) [<https://perma.cc/MGA9-CA4C>].

33. Marihuana Tax Act of 1937, Pub. L. No. 75–238, 50 Stat. 551 (repealed 1971).

34. *Id.*

sterilized seed of such plant which is incapable of germination.<sup>35</sup>

In the Marihuana Tax Act of 1937, Congress created two classes of cannabis, as it did more recently in the 2018 Farm Bill.<sup>36</sup> Under the 1937 system, Congress defined “marihuana” as all parts of the plant that would practically have intoxicating or therapeutic effects.<sup>37</sup> Before THC and CBD were even discovered in the cannabis plant, Congress created a classification system for the cannabis plant that regulated the parts of cannabis that can get a user “high” under the tax but allowed the hemp or industrial elements of the cannabis plant to remain unregulated by the taxation scheme.<sup>38</sup>

In the ensuing years, additional restrictions were placed on the use of cannabis. In 1942, the United States Pharmacopeial Convention removed cannabis from the U.S. Pharmacopeia.<sup>39</sup> With little to no officially recognized therapeutic value given to cannabis as a result, Congress moved in the 1950s to pass the Boggs Act and the Narcotic Control Act, which included cannabis among the restricted substances and set minimum sentences and fines for unauthorized possession.<sup>40</sup>

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35. *Id.*

36. *Id.*; Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

37. Marihuana Tax Act of 1937, Pub. L. No. 75-238, 50 Stat. 551 (repealed 1971); *see generally* Zerrin Atakan, *Cannabis, a complex plant: different compounds and different effects on individuals*, 2 THERAPEUTIC ADVANCES IN PSYCHOPHARMACOLOGY 241 (2012) (provides scientific information about intoxicating or therapeutic effects of cannabis).

38. THC and CBD were first isolated and discovered in the early 1960's by Raphael Mechoulam, an Israeli organic chemist. Meir Bailer, *Raphael Mechoulam and the history of cannabis research*, INT'L LEAGUE AGAINST EPILEPSY (2019), <https://www.ilae.org/journals/epigraph/epigraph-vol-21-issue-1-winter-2019/raphael-mechoulam-and-the-history-of-cannabis-research> [<https://perma.cc/A29X-F5RR>].

39. *About Cannabis Policy*, ALCOHOL POL'Y INFO. SYS., <https://alcoholpolicy.niaaa.nih.gov/about-cannabis-policy> (last visited Jan. 30, 2022) [<https://perma.cc/S992-GX5F>]. The U.S. Pharmacopeia is compendium of drug information detailing standards for drug manufacturing. The United States Pharmacopeial Convention functions independently from the federal government, however the U.S. Pharmacopeia guides standards and safety enforcement by federal agencies. *U.S. Pharmacopeia: Building trust for 200 years*, U.S. PHARMACOPEIA, <https://www.usp.org/200-anniversary/usp-building-trust-for-200-years> (last visited Jan. 30, 2022) [<https://perma.cc/HA9U-3BJZ>].

40. Boggs Act of 1951, Pub. L. No. 82-255, 65 Stat. 767, (1951) (repealed 1970); Narcotic Control Act of 1956, Pub. L. No. 84-728, 70 Stat. 567 (1956); *Marijuana Timeline*, *supra* note 28. It notable that cannabis is not a narcotic even though its criminalization fell under the Narcotics Control Act. John B. Murray, *Marijuana's effects on human cognitive functions, psychomotor functions, and personality*, 113 J. GEN. PSYCH. 23, 23 (1985).

### *B. The Total Cannabis Prohibition Period*

In 1969, the Marihuana Tax Act was deemed unconstitutional by the United States Supreme Court in the case *Leary v. United States*.<sup>41</sup> Congress reacted quickly and passed the Controlled Substances Act (CSA) in 1970, which was signed into law by President Richard Nixon.<sup>42</sup> The CSA transformed the way the federal government regulated cannabis and initiated the period of total prohibition of cannabis by making cannabis entirely illegal in the United States.<sup>43</sup> As part of the legislation, Congress created the Drug Enforcement Agency (DEA) to enforce the drug bans.<sup>44</sup> A scheduling system of substances was incorporated into the legislation which the FDA was tasked to manage with the DEA.<sup>45</sup>

The substances in the system are called controlled substances and are “divided into categories known as Schedules I through V based on their medical utility and their potential for abuse and dependence.”<sup>46</sup> The CSA initially “categorized marijuana as a Schedule I substance, meaning it was considered to have no acceptable medical use and was among the class of drugs having the highest potential for abuse.”<sup>47</sup> Neither Congress nor the Executive Branch have moved to reschedule marijuana from a Schedule I drug to a different classification since it was placed there by the CSA in 1970.<sup>48</sup> However, the FDA did not have any regulatory power over the

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41. *Leary v. United States*, 395 U.S. 6 (1969). Leary was arrested for violating the Marihuana Tax Act of 1937 when he did not disclose the possession of marijuana to a US customs officer in Texas. Marijuana was illegal at the time under Texas state law. The Supreme Court unanimously held the Marihuana Tax Act of 1937 violated citizens’ Fifth Amendment rights because compliance with the federal statute required citizens to self-incriminate. *Id.*

42. Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970).

43. *Id.*

44. Joanna R. Lampe, *The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress*, CONG. RSCH SERV. (Feb. 5, 2021), <https://sgp.fas.org/crs/misc/R45948.pdf> [<https://perma.cc/93DZ-WB8S>].

45. *Id.*

46. *Id.*

47. *About Cannabis Policy*, *supra* note 39.

48. The DEA’s Orange Book lists all controlled substances. *Controlled Substances - Alphabetical Order*, U.S. DRUG ENF’T AGENCY (Nov. 18, 2021), [https://www.deadiversion.usdoj.gov/schedules/orangebook/c\\_cs\\_alpha.pdf](https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf) [<https://perma.cc/C8SG-8RXN>]; The U.S. Department of Health and Humans Services Secretary can unilaterally legalize cannabis: “[I]f the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.” 21 U.S.C. § 811(b).



cannabis plant because all forms of cannabis fell under Schedule I of the CSA and were made illegal.

### C. *The Disintegration of Prohibition*

If you are to view the entire history of restrictions, bans, criminalization, and other anti-cannabis regulation on a timeline, the passage of the CSA would mark the most restrictive point. Following the enactment of the CSA and the establishment of total prohibition of cannabis, states began to move to lower the criminal liability for possession.<sup>49</sup>

Beyond making changes to the criminal status of cannabis at the state level, some states also began to legalize cannabis for medical use, starting with California in 1996.<sup>50</sup> Currently, most U.S. states have legalized at least some form of cannabis (medicinal or recreational) within their borders.<sup>51</sup> Recreational adult use of cannabis was first legalized by Colorado and Washington state in 2012.<sup>52</sup> Currently, state laws legalizing cannabis are an extremely complex patchwork of regulations that strongly regulate the

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49. For example, Texas passed a law that possession of four ounces or less a misdemeanor. Griffin Smith Jr., *How the New Drug Law Was Made*, TEX. MONTHLY (Sept. 1973), <https://www.texasmonthly.com/news-politics/how-the-new-drug-law-was-made/> [<https://perma.cc/VB2C-ZXDX>]. In 1973, Oregon became the first state to decriminalize cannabis. Andrew Selsky, *Oregon 1st state to decriminalize possession of drugs*, AP NEWS (Feb. 1, 2021), <https://apnews.com/article/oregon-decriminalize-drug-possession-6843f93c3d55212e0ffb8b93be9196> [<https://perma.cc/8U54-KTGX>]. Between 1973 and 1978 11 states reduced criminal sanctions in some way for possession of small amount of cannabis. The states that did so are as follows: Oregon (1973), Colorado (1975), Alaska (1975), Ohio (1975), California (1976), Maine (1976), Minnesota (1976), Mississippi (1977), New York (1977), North Carolina (1977), and Nebraska (1978). Rosalie Pacula et al., *Marijuana Decriminalization: What Does It Mean for the United States?*, NAT'L BUREAU OF ECON. (May 2003), [http://www.rand.org/content/dam/rand/pubs/working\\_papers/2004/RAND\\_WR126.pdf](http://www.rand.org/content/dam/rand/pubs/working_papers/2004/RAND_WR126.pdf) [<https://perma.cc/JN22-QNWP>].

50. *Medicinal Marijuana Laws*, SACRAMENTO CNTY. PUB. L. LIBR. (May 2021), <https://saclaw.org/articles/marijuana-laws-in-california-ed/> [<https://perma.cc/9REY-HA3S>].

51. "As of May 18, 2021, 36 states and four territories allow for the medical use of cannabis products. In November 2020, voters in Mississippi passed a ballot initiative to allow for medical use, but it was overturned by the state supreme court on May 14, 2021, and is not counted" in the totals listed. *State Medical Cannabis Laws*, NAT'L CONF. OF STATE LEGISLATURES (Jan. 4., 2022), <https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> [<https://perma.cc/TYX3-3FHL>].

52. John Hudak & Philip A. Wallach, *Legal Marijuana: Comparing Washington and Colorado*, BROOKINGS (July 8, 2014), <https://www.brookings.edu/blog/fixgov/2014/07/08/legal-marijuana-comparing-washington-and-colorado/> [<https://perma.cc/ZPA2-475C>]; "21 states, two territories and the District of Columbia have enacted legislation to regulate cannabis for nonmedical use." *State Medical Cannabis Laws*, *supra* note 51.

market and often place variable conditions of to whom, where, and how the plant can be bought, sold, processed, and consumed.<sup>53</sup>

*D. Designer Drugs, Spice, and the Federal Analogue Act*

During the mid-1980's, so called designer drugs rose in popularity.<sup>54</sup> Designer drugs are substances that are created through chemistry “to mimic the effects of drugs that are often notorious and banned.”<sup>55</sup> In response, Congress passed the Federal Analogue Act in 1986.<sup>56</sup> The Act “allows many synthetic drugs to be treated as controlled substances if they are proven to be chemically and/or pharmacologically similar to a Schedule I or Schedule II controlled substance.”<sup>57</sup>

However, this did not stop the rise of new designer drugs. In the early 2010's, synthetic marijuana known as “spice” or “K2” rose in popularity, prompting Congress to pass and President Obama to sign the Synthetic Drug Abuse Prevention Act as a part of the FDA Safety and Innovation Act of 2012.<sup>58</sup> This legislation placed “26 types of synthetic cannabinoids and cathinones into Schedule I of the Controlled Substances Act (CSA).”<sup>59</sup> The legislation removed any ambiguity as to the legality of this class of designer drugs. It is important to note that while synthetic marijuana may have the name “marijuana” that may appear to indicate a connection to Delta-9 THC, they are not similar in chemical composition to real cannabinoids.<sup>60</sup> Instead, synthetic marijuana is comprised of “a collection of numerous laboratory chemicals that interact with the cannabinoid receptor in the brain to mimic marijuana to induce a marijuana-like high.”<sup>61</sup>

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53. *State Medical Cannabis Laws*, *supra* note 51.

54. Gregory Kau, *Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron*, 156 U. PA. L. REV. 1077, 1079 (2008) (*see* footnote 10).

55. *Designer Drugs Addiction and Treatment*, AM. ADDICTION CTRS. (Jan. 19, 2021), <https://americanaddictioncenters.org/designer-drugs-addiction> [<https://perma.cc/6RUT-KFAL>].

56. 21 U.S.C. § 813.

57. *Synthetic Drugs (a.k.a. K2, Spice, Bath Salts, etc.)*, OBAMA WHITE HOUSE, <https://obamawhitehouse.archives.gov/ondcp/ondcp-fact-sheets/synthetic-drugs-k2-spice-bath-salts> [<https://perma.cc/34PJ-STGN>]. (last visited Feb. 1, 2022).

58. *Id.*

59. *Id.*

60. Ann M. Lemp et al., *Top 10 Facts You Need to Know About Synthetic Cannabinoids: Not So Nice Spice*, 129 AM. J. MED. 240, 240 (Mar. 2016).

61. *Id.*

### *E. The 2018 Farm Bill*

The passage of the 2018 Farm Bill marked the most significant alteration to federal cannabis regulation since Richard Nixon signed the CSA in 1970. As it does every five years, the 115<sup>th</sup> Congress passed the 2018 Farm Bill which “sets national agriculture, nutrition, conservation, and forestry policy.”<sup>62</sup>

It is notable that the driving force behind the 2018 Farm Bill’s cannabis regulatory reforms was then-Senate Majority Leader Mitch McConnell.<sup>63</sup> Legalizing commercial hemp was an important priority of McConnell, which he first introduced in the 115<sup>th</sup> Congress as the Hemp Framing Act of 2018<sup>64</sup>— the major elements of which were incorporated into the 2018 Farm Bill. Legalizing hemp was popular in McConnell’s home state of Kentucky which is “one of the best places to cultivate hemp in the world, and pre-prohibition the state had a robust hemp sector.”<sup>65</sup> As explored in this note,

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62. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

63. John Hudak, *The Farm Bill, hemp legalization and the status of CBD: An explainer*, BROOKINGS (Dec. 14, 2018), <https://www.brookings.edu/blog/fixgov/2018/12/14/the-farm-bill-hemp-and-cbd-explainer/> [<https://perma.cc/AF73-FS3H>].

64. S. 2667, 115th Cong. (2018).

65. Hudak, *supra* note 63. McConnell has consistently polled poorly with Kentucky residents, with his approval rating in 2018 estimated to be around 30 percent. Lisa Autry, *WKU Poll Rates Favorability of Mitch McConnell, Rand Paul*, WVXU (Apr. 23, 2018), <https://www.wvxu.org/politics/2018-04-23/wku-poll-rates-favorability-of-mitch-mcconnell-rand-paul> [<https://perma.cc/P3TY-DJZY>]. Democrats had been gaining ground politically statewide, as evidenced by the narrow 2019 victory of Democrat Andy Beshear over incumbent Republican Governor Matt Bevin. Phillip M. Bailey, *Democrat Andy Beshear declares victory over Matt Bevin in governor's race. Bevin doesn't concede*, COURIER J. (Nov. 5, 2019), <https://www.courier-journal.com/story/news/politics/elections/kentucky/2019/11/05/kentucky-governors-race-2019-andy-beshear-leads-incumbent-matt-bevin/4096321002/> [<https://perma.cc/4B2X-6ZRG>]. Senator McConnell may have wanted to have a popular win on hemp to buoy support in his upcoming 2020 reelection campaign in the face of increased competition from highly funded Democratic candidate Amy McGrath. *See generally* Hudak, *supra* note 63, stating that

Without Mr. McConnell’s efforts, the hemp provisions would never had found their way into the legislation initially. And although his position as Senate leader gave him tremendous institutional influence over the legislation, he went a step further by appointing himself to the conference committee that would bring the House and Senate together to agree on a final version. McConnell understood much about this issue. First, he knows hemp doesn’t get you high and that the drug war debate that swept up hemp was politically motivated, rather than policy-oriented. Second, Kentucky—the leader’s home state—is one of the best places to cultivate hemp in the world, and pre-prohibition the state had a robust hemp sector. Third, the grassroots interest in this issue was growing in Kentucky, and McConnell knows that his role as Senate Majority Leader hangs in the balance in

the provisions relating to cannabis in the 2018 Farm Bill were poorly drafted and created consequences that were likely unintended and unimagined by Senator McConnell.<sup>66</sup>

When the 2018 Farm Bill legalized hemp, it used a very specific phrasing to define what cannabis would fall under the definition of hemp and made Delta-9 THC concentration the litmus test as to whether a cannabis substance was hemp.<sup>67</sup> It defined hemp as:

the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.<sup>68</sup>

This essentially created two classes of cannabis in the eyes of the federal government.<sup>69</sup> The first class is called “hemp” and encompasses the strains of cannabis that contains 0.3% or less Delta-9 THC concentration within the plant.<sup>70</sup> The other class of cannabis, which can be understood as

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2020, as does his Senate seat as he faces re-election that same year. McConnell emerges from the Farm Bill as a hemp hero, but advocates should be hesitant to label him a cannabis champion; Leader McConnell remains a staunch opponent of marijuana reform and his role in the Senate could be the roadblock of Democratic-passed legislation in the 116th Congress.

*See generally* Morgan Watkins, *Mitch McConnell defeats Democrat Amy McGrath to keep his seat in the Senate*, COURIER J. (Nov. 3, 2020, 8:06 PM), <https://www.courier-journal.com/story/news/politics/elections/kentucky/2020/11/03/mitch-mcconnell-wins-over-democratic-challenger-amy-mcgrath/6074895002/> [<https://perma.cc/H9Z8-HKFF>] (Mitch McConnell ended up winning the 2020 Kentucky race for U.S. Senate and was reelected).

66. There is no evidence in the congressional record or through the senator’s public statement that Mitch McConnell intended to legalize CBD, Delta-8 THC, or other cannabinoids. The language of the initial bill introduced by McConnell in the 115th Congress stated the purpose of the changes to “provide for State and Tribal regulation of hemp production, and for other purposes,” not to reschedule hundreds of known and unknown compounds that naturally occur within the cannabis plant that are not Delta-8 THC. Hemp Farming Act of 2018, S. 2667, 115th Cong. (2018); Hudak, *supra* note 63; Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490; *see* Lester Black, *How Mitch McConnell Accidentally Created An Unregulated THC Market*, FIVETHIRTYEIGHT (Oct. 18, 2021), <https://fivethirtyeight.com/features/how-mitch-mcconnell-accidentally-created-an-unregulated-thc-market/> [<https://perma.cc/8QLK-N6T8>].

67. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

68. *Id.*

69. *Id.*

70. *Id.*

“marijuana,” contains all strains of the cannabis plant that contain greater than 0.3% Delta-9 THC concentration and continues to be classified as a Schedule I drug under the CSA.<sup>71</sup> The class of cannabis defined as hemp was made legal under this new classification scheme.<sup>72</sup> Congress did this because while the cannabis plant has compounds in it that have mind altering, intoxicating, and medicinal effects, like delta-9 tetrahydrocannabinol, the plant also has industrial value.<sup>73</sup>

The regulatory scheme hinges on the 0.3% bright line rule, which permits cannabis plants and products that have less than 0.3% of Delta-9 THC.<sup>74</sup> However, given that the percentage of Delta-9 THC is the only factor included within the 2018 Farm Bill to determine whether cannabis plant strains or “derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not” are restricted under Schedule I of the CSA, it clearly stands to reason that all other parts of cannabis that have lower than 0.3% of Delta-9 THC are legal.<sup>75</sup> This creates a significant issue because the “cannabis is a complex plant” and beyond Delta-9 THC there are “over 400 chemical entities of which more than 60 of them are cannabinoid compounds, some of them with opposing effects.”<sup>76</sup> Essentially, plainly reading the language of the bill, all of these chemical entities, including all non-Delta-9 THC cannabinoids were legalized federally.<sup>77</sup> A gigantic loophole had been created, which allowed for the legal commercial development of the CBD and later Delta-8 markets.

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71. *Id.*

72. *Id.*

73. The U.S. has a history of growing hemp for industrial purposes. During the 1600s, the Jamestown colonists were required by royal decree to grow hemp to be used in cordage and canvas for ships. As recently as the 1940s, the federal government briefly lifted elements of the Marihuana Tax Act and encouraged American farmers to grow hemp for ships’ rigging during World War II. Carey Reed, *8 things you didn’t know about hemp*, PBS NEWSHOUR (Oct. 17, 2015), <https://www.pbs.org/newshour/nation/8-things-didnt-know-hemp> [https://perma.cc/R9AN-XCF6].

74. Delta-9 THC is the compound that gets a user “high” when consuming cannabis. *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, NATIONAL CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, <https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know> (last visited Oct. 2, 2021) [https://perma.cc/K3G5-QXS8].

75. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

76. Atakan, *supra* note 37.

77. Cannabinoids are a classification of substances found within the cannabis plant; the various forms of THC and CBD are cannabinoids. *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, *supra* note 74.

*F. CBD – The First Cannabinoid Loophole Exploited*

Following the legalization of hemp, budding entrepreneurs across the nation identified the loophole that had been created by Congress.<sup>78</sup> All non-Delta-9 cannabinoids were apparently legal. The first cannabinoid that gained widespread popularity was cannabidiol or CBD.<sup>79</sup> According to a survey in April of 2020, around one-in-three U.S. adults reported to use CBD supplements.<sup>80</sup> The total value of national CBD sales in 2018 was \$535 million.<sup>81</sup> “The total value of the market has increased dramatically since the creation of the loophole which made CBD legal federally.”<sup>82</sup> In 2022, total sales of CBD products are projected to exceed \$1.9 billion.<sup>83</sup>

Supporters of CBD claim that it can serve as an all-natural treatment for “ailments as diverse as inflammation, pain, acne, anxiety, insomnia, depression, post-traumatic stress and even cancer.”<sup>84</sup> While CBD is often sold in the form of a supplement that may be marketed as a modern-day patent medicine, it is also infused in various consumer products.<sup>85</sup> These infused products range from Willie Nelson’s brand of CBD infused coffee to dog toys and bath bombs.<sup>86</sup>

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78. Mike Sill, *The Future of the CBD Industry in 2022 and Beyond*, FORBES BUSINESS COUNCIL (Oct. 21, 2021), <https://www.forbes.com/sites/forbesbusinesscouncil/2021/10/21/the-future-of-the-cbd-industry-in-2022-and-beyond/?sh=252e87d125fd> [<https://perma.cc/35PG-URE9>].

79. Peter Grinspoon, *Cannabidiol (CBD)-what we know and what we don't*, HARV. HEALTH PUBLISHING (Sept. 24, 2021), <https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476> [<https://perma.cc/Q4S2-56S8>].

80. Matej Mikulic, *Percentage of U.S. adults who use cannabidiol supplements as of 2020*, STATISTA (Dec. 8, 2020), <https://www.statista.com/statistics/1182730/percentage-american-adults-use-cbd-supplements/> [<https://perma.cc/9NSY-P6ZT>].

81. Matej Mikulic, *Total U.S. cannabidiol (CBD) product sales from 2014 to 2022*, STATISTA (Sept. 10, 2021), <https://www.statista.com/statistics/760498/total-us-cbd-sales/> [<https://perma.cc/2DCC-XVVS>].

82. *Id.*

83. *Id.*

84. Alex Williams, *Why is CBD Everywhere?*, N.Y. TIMES (Oct. 27, 2018), <https://www.nytimes.com/2018/10/27/style/self-care/cbd-benefits.html> [<https://perma.cc/TSJ7-GG27>].

85. *Id.* Given that many of the CBD products on the market are marketed to consumers as supplements, even if the FDA began to regulate cannabinoids, dietary supplements and claims used in their marketing are subject to less scrutiny from the FDA than food or drugs. *FDA 101: Dietary Supplements*, FDA (June 2, 2022), <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements#:~:text=For%20most%20claims%20made%20in,it%20appears%20on%20the%20product> [<https://perma.cc/73P8-6HYQ>].

86. Williams, *supra* note 84.

Critics of the CBD market have begun to organize in opposition to the lack of FDA oversight over CBD. The National Consumer League has launched a project called Cannabis Consumer Watch.<sup>87</sup> One of the qualms that consumer groups have with the CBD market beyond its often-unproven medical treatment claims is that mislabeling of products is rampant.<sup>88</sup> The FDA reported to Congress that it sampled CBD products on the market and found that most products did not contain the amount of CBD indicated on the label.<sup>89</sup>

### G. *The Rise of Delta-8*

As the CBD market has grown, hemp growers and entrepreneurs found themselves with surplus CBD.<sup>90</sup> So, they turned their attention toward developing a market for another cannabinoid, Delta-8-tetrahydrocannabinol, commonly referred to as “Delta-8” or “Delta-8 THC.”<sup>91</sup> Delta-8 occurs naturally within the cannabis plant, but in very low quantities; thus, much of the Delta-8 on the market is actually derived from CBD through chemical processes.<sup>92</sup> Delta-8 quickly became popular in late 2020 and early 2021, and constitutes one of the fastest growing segments of the hemp market.<sup>93</sup>

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87. *About Us*, CANNABIS CONSUMER WATCH, <https://www.cannabiswatch.org/about> (last visited Feb. 8, 2022) [<https://perma.cc/YN3G-KFKR>].

88. *Suggested Solutions*, CONSUMERS FOR SAFE CBD, <https://www.4safecbd.org/4-suggested-solutions> (last visited Feb. 8, 2022).

89. Only “94% contained CBD . . . 18% contained less than 80% of the amount of CBD indicated, 45% contained within 20% of the amount listed, 37% contained more than 20% of the amount of CBD indicated, 49% contained THC or THCA at levels above the lowest concentration that can be detected.” Gregory S. Kaufman, *CBD Industry Caught Between Regulators & Law Enforcement*, CANNABIS INDUST. J. (Sept. 9, 2020), <https://cannabisindustryjournal.com/tag/congress/> [<https://perma.cc/YV3R-9JTQ>].

90. Jessica McKeil, *How Delta-8 THC is Made in the Lab*, CANNABIS TECH. (Mar. 29, 2021), <https://www.cannabistech.com/articles/how-delta-8-is-made-in-the-lab/> [<https://perma.cc/7LHA-NWAS>].

91. *Id.*

92. *Id.* All cannabinoids start out as one compound called cannabigerolic acid or CBGA, which is referred to as the “mother of all cannabinoids.” *Id.* During the course of the cannabis plant’s life cycle, CBGA develops into the various cannabinoids that exist in the plant like CBD, Delta-8, and Delta-9 in varying concentrations based on the genetics of the plant, environmental exposures, and stress. *Id.* “Because cannabinoids are remarkably similar in molecular structure, bringing this natural tendency to convert from one to another into the laboratory is relatively straightforward.” *Id.*

93. Jennifer Peltz, *A new cannabis strain is drawing praise in the industry and scrutiny among lawmakers*, FORTUNE (July 28, 2021), <https://fortune.com/2021/07/28/delta-8-thc-chemical-popularity->

The appeal of Delta-8 is that its consumption or usage creates an effect very similar to that experienced by consuming or using more traditional cannabis which has high concentrations of Delta-9 THC.<sup>94</sup> Delta-8 is colloquially referred to as “diet weed,” considered to be a slightly milder version of Delta-9.<sup>95</sup> This differs greatly from CBD which does not have psychoactive effects that get a user “high.”<sup>96</sup> Essentially, the commercial appeal of Delta-8 is that it provides a federally legal and nearly identical experience to that of federally illegal Delta-9. While there is little research on the effects of the Delta-8, a recent leading study done on the compound comparing it to Delta-9 indicates that the experience provided by Delta-8 may be superior in some respects to that of Delta-9.<sup>97</sup>

In August 2020, the DEA released an Interim Final Rule (IFR) attempting to address the loophole that Delta-8’s legality appears to rest upon and stated that “[a]ll synthetically derived tetrahydrocannabinols remain Schedule I controlled substances.”<sup>98</sup> However, it has done little to nothing to enforce this, and it unclear whether a court would actually find that Delta-8 is a “synthetically derived tetrahydrocannabinol” given that it occurs naturally within the cannabis plant. As noted, the Delta-8 for sale on the market is typically manufactured by the conversion of CBD to Delta-8 through chemical processes. This stands in contrast to the “designer drugs” like K2 and spice which are entirely created in a lab, not through the conversion of one cannabinoid to another.

While the federal government has done little to interfere with the Delta-8 market, many state governments have reacted quickly to the compound.

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cannabis-industry-lawmakers-scrutiny-cbd/ [https://perma.cc/E8SL-T7CR].

94. *Id.*

95. Short Wave, *The Science Of The Delta-8 Craze*, NPR, at 04:51 (Jan. 3, 2022), <https://www.npr.org/2021/12/16/1064878865/the-science-of-the-delta-8-craze> [https://perma.cc/4A9U-SMUA].

96. *Can You Get High from CBD or CBD Oil?*, HEALTHLINE, <https://www.healthline.com/health/does-cbd-get-you-high> (last visited Feb. 8, 2022) [https://perma.cc/4A7F-SEB3].

97. Jessica S. Kruger & Daniel J. Kruger, *Delta-8-THC: Delta-9-THC's nicer younger sibling?*, 4 J. OF CANNABIS RSCH. (Jan. 4, 2022), <https://j cannabisresearch.biomedcentral.com/articles/10.1186/s42238-021-00115-8> [https://perma.cc/M6EM-LBBF]. “Delta-8-THC may provide much of the experiential benefits of delta-9-THC with lesser adverse effects. Future systematic research is needed to confirm participant reports, although these studies are hindered by the legal statuses of both delta-8-THC and delta-9-THC.” *Id.*

98. DEA Implementation of the Agriculture Improvement Act of 2018, 21 C.F.R. § 1308, § 1312 (2020).



As of August 2021, twenty-one states have blocked the sale of Delta-8.<sup>99</sup> Many proponents of bans cite a lack of research into the compound's effects and health risks.<sup>100</sup> However, some researchers have noted issues with the state-level response.<sup>101</sup> Daniel J. Kruger, PhD, a research investigator in the Population Studies Center at the University of Michigan who co-authored the largest study on Delta-8 thus far, has stated that, "It's paradoxical that different states and municipalities are opening up to [D]elta-9, it's becoming more available and increasingly legalized, and yet they're putting the brakes on [D]elta-8, even though it seems to have a better profile in terms of its effects."<sup>102</sup>

While CBD has been popular longer than Delta-8 without significant federal and state interference, it is unlikely that the federal and state governments will indefinitely continue to allow the Delta-8 market to remain utterly unregulated.<sup>103</sup> Not only do federal and state governments want the market regulated for public health and safety concerns, but the legal marijuana industries in states with varying degrees of legalization have pushed back on the lack of regulation of Delta-8, which does not require licensing to sell in near direct competition to their THC products.<sup>104</sup> There will likely be changes to its regulatory scheme soon. However, if those changes are narrowly tailored, they may only have a strong control over the market for intoxicating imitation Delta-9 THC for a short period. New cannabinoids like Delta-10 and Delta-O are already entering the market in

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99. Alex Malyshev & Sarah Ganley, *Controlling cannabis and the classification of Delta-8 THC*, REUTERS (Sept. 22, 2021), <https://www.reuters.com/legal/litigation/controlling-cannabis-classification-delta-8-thc-2021-09-22/> [<https://perma.cc/6S9B-H6KX>].

100. Britt E. Erikson, *Delta-8-THC craze concerns chemists*, 99 CHEM. & ENG'G NEWS (Aug. 30, 2021), <https://cen.acs.org/biological-chemistry/natural-products/Delta-8-THC-craze-concerns/99/i31> [<https://perma.cc/NQN2-GZHJ>].

101. David J. Hill, *Study: Users say delta-8-THC is delta-9's 'nicer younger sibling'*, U. BUFF. (Jan. 12, 2022), <http://www.buffalo.edu/news/releases/2022/01/009.html> [<https://perma.cc/QR77-S5QQ>].

102. *Id.*

103. Chris Roberts, *The Feds Are Coming For Delta-8 THC*, FORBES.COM <https://www.forbes.com/sites/chrisroberts/2021/09/17/the-feds-are-coming-for-delta-8-thc/?sh=2067c3156d27> (last visited Oct. 2, 2021) [<https://perma.cc/33E4-BKG9>]. Delta-8 is in part unlikely to continue to be as unregulated as it is because it is a psychoactive compound that has effects similar to highly regulated Delta-9 THC. See Amber Smith, *What Is Delta 8 THC? Here's Everything You Need to Know*, DISCOVER MAG. (Sept. 21, 2022), <https://www.discovermagazine.com/health/what-is-delta-8-the-heres-everything-you-need-to-know> [<https://perma.cc/P7N8-FQ5H>].

104. Roberts, *supra* note 103.

the hope of conquering the market if broader regulation of Delta-8 disrupts the legality and supply alternative quasi-legal intoxicating cannabinoids.<sup>105</sup>

## II. ANALYSIS

While some argue that Delta-8 was not made legal federally after the passage of the 2018 Farm Bill, the federal government has not substantially acted in a way to indicate that Delta-8 products are illegal.<sup>106</sup> Additionally, lawyers in the cannabis regulation space argue that “Delta-8 THC is a hemp-derived substance and, as a result, is exempted from the definition of marijuana pursuant to the 2018 Farm Bill.”<sup>107</sup> Pending any additional action from Congress or the courts, it generally appears that Delta-8 is legal federally. However, there are significant health and economic justice concerns with the federal regulatory framework of Delta-8 THC as it currently stands.

### *A. Potential Legal Issues Implicated*

Since Delta-8 only recently became popular, there has not been much action by the federal government to do anything about the compound. The federal government has taken no meaningful action in attempting to designate the compound illegal. Should the federal government choose to attempt to eliminate the Delta-8 market, it may have challenges doing so without congressional action due to how the 2018 Farm Bill was drafted.

The regulatory scheme created in the Marihuana Tax Act of 1937 was arguably the goal of the 2018 Farm Bill – allow cannabis to be used for industrial purposes but also to restrict recreational and therapeutic uses.<sup>108</sup> As described earlier, the way that the 2018 classification scheme was based on the percentage of Delta-9 THC has created a loophole that has potentially made CBD, Delta-8 THC, and other cannabinoids federally unregulated.<sup>109</sup> Under the 1937 Marihuana Tax Act scheme, CBD, Delta-8 THC, and other

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105. Max Savage Levenson, *Meet THC-O, a hemp-derived compound three times stronger than THC*, LEAFLY, <https://www.leafly.com/news/cannabis-101/what-is-thc-o> (Aug. 19, 2021) [<https://perma.cc/9XHJ-4YR7>].

106. Malyshev, *supra* note 99.

107. *Id.*

108. Marihuana Tax Act of 1937, Pub. L. No. 75-238, 50 Stat. 551 (repealed 1971).

109. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

cannabinoids would fall under the regulation, while still allowing legal development of the hemp market. Delta-8 THC would fall under the definition of taxed “marihuana” because it is a “compound” from the cannabis plant and thus would be restricted.<sup>110</sup> If Congress understood cannabis well enough in 1937 to create this regulatory scheme, why did Congress choose to create so much confusion in the hemp legalization provision in the 2018 Farm Bill?

It is reasonable to assume that there was not a master plan to legalize Delta-8 by members of Congress or special interests. Many chemists were not even familiar with the compound, in part due to how little is generally known about the cannabis plant due to restrictions on research. It is likely that the Congressional staff lawyers who drafted the provisions thought they better understood the science of the cannabis plant than they really did.<sup>111</sup> Instead of using language similar to that in the Marihuana Tax Act of 1937, they opted to make the distinguishing characteristic of illegal marijuana Delta-9 THC.

One potential avenue for attacking the legality of Delta-8 would be to assert that “Delta-8 violates the Federal Analogue Act.”<sup>112</sup> Delta-8 THC has a similar but weaker effect in comparison to Delta-9 THC, earning it the nickname “diet weed” due to that significantly lower potency.<sup>113</sup> It is

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110. *Id.*

111. In the 2018 Farm Bill, Congress defined cannabis as the species *Cannabis sativa L.*, and specifically and narrowly defining hemp as this specific species may be inaccurate according to some botanists. It likely would have been more accurate to have defined hemp using only the more general genus name *Cannabis*. See Pollio, *supra* note 2; Geoff Watts, *Science Commentary: Cannabis Confusions*, 332 BRIT. MED. J. 175, 175-76 (Jan. 21, 2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1336775/pdf/bmj33200175.pdf> [<https://perma.cc/VPR9-5M7X>].

112. Malyshev, *supra* note 99. The term “controlled substance analogue” means

a substance— (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

21 U.S.C. § 802(32).

113. Short Wave, *supra* note 95.

entirely possible that a court might find Delta-8 THC to violate the Federal Analogue Act. However, the language of the 2018 Farm Bill does very clearly, specifically, and narrowly identify Delta-9 as the only substance in cannabis being regulated. If this argument is accepted, Delta-8 cannot violate the Federal Analogue Act, because Congress made it legal. Thus, it does not have a controlled substance analogue. The fact that Delta-8 occurs naturally in cannabis and is distilled from the legal hemp plants further cuts in favor of Delta-8 not falling under the purview of the Federal Analogue Act given that past marijuana analogues like synthetic marijuana or “spice” are artificially created in laboratories.<sup>114</sup>

### *B. Health and Safety Concerns*

Because there is no federal regulation currently on the sale of Delta-8 THC, there are numerous health and safety concerns with public consumption of the compound. The chemistry processes that isolate and distill Delta-8 from legal hemp are not standardized, and some of the processes used can create toxic byproducts that can end up in the final concentrate.<sup>115</sup>

The FDA is concerned about many reports of people getting sick from Delta-8 consumption.<sup>116</sup> Between January 1, 2021—the date that delta-8 THC product code was added to its database—and February 28, 2022, U.S. poison control centers received 2,362 exposure cases of delta-8 THC products.<sup>117</sup> The FDA is also concerned about the marketing that is being used by Delta-8 products.<sup>118</sup> Delta-8 companies are sometimes marketing

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114. *Id.* at 07:46.

115. *Id.* at 07:10.

116. *FDA 5 Things to Know*, *supra* note 7.

117. *Id.*

Of the 2,362 exposure cases: 58% involved adults, 41% involved pediatric patients less than 18 years of age, and 1% did not report age. 40% involved unintentional exposure to delta-8 THC and 82% of these unintentional exposures affected pediatric patients. 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were pediatric patients. One pediatric case was coded with a medical outcome of *death*.

*Id.*

118. *Id.*

their products for “therapeutic or medical uses.”<sup>119</sup> These practices harken back to the era of patent medicines, which in part prompted the establishment of the FDA. Making unapproved claims like those that some Delta-8 companies are making violates federal law.<sup>120</sup>

Finally, Delta-8 THC is often sold in the form of gummies, chocolates, and beverages that can be appealing to children.<sup>121</sup> Children are accidentally consuming the compound and getting sick.<sup>122</sup> If the FDA exercised regulatory power over Delta-8, it would be able to regulate these types of products by making them less appealing to children and by mandating warnings on packaging.

### III. PROPOSAL

When the 2018 Farm Bill legalized hemp, the FDA gained jurisdiction over regulation of the plant and its byproducts. However, it has not exercised that power over Delta-8, CBD, or any other hemp derived product. Essentially, when asked to regulate Delta-8 THC, the FDA points to the DEA as the agency responsible for regulation of hemp products like Delta-8 THC because the DEA maintains that Delta-8 is illegal under the Controlled Substances Act.<sup>123</sup> However, the DEA has not meaningfully acted on its assertion.<sup>124</sup> There exists a regulatory void that neither the FDA nor the DEA are filling.

The FDA must do more to regulate the hemp market, and Congress must clearly enable it to do so. In 2021, the Hemp Access and Consumer Safety Act was introduced into Congress.<sup>125</sup> The bill was introduced by Senators Wyden, Paul, and Merkley, all of whom were original co-sponsors of the Hemp Farming Act that was incorporated into the Farm Bill of 2018.<sup>126</sup> The Hemp Access and Consumer Safety Act would require the FDA to regulate

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119. *Id.*

120. *Id.*

121. Trisha Koriath, *Accidental exposure risks reported in children from delta-8 THC in cannabidiol products*, AM. ACAD. PEDIATRICS (Nov. 1, 2021), <https://publications.aap.org/aapnews/news/17433> [<https://perma.cc/TA9P-TF76>].

122. *Id.*

123. Black, *supra* note 66.

124. *Id.*

125. Hemp Access and Consumer Safety Act, S. 1698, 117th Cong. (2021).

126. *Id.*; Hemp Farming Act of 2018, S. 2667, 115th Cong. (2018).

CBD and hemp-derivative products like Delta-8, but would not change the definition of hemp that was created in the 2018 Farm Bill.<sup>127</sup>

Some may argue that not enough is known about the health and safety risks associated with Delta-8 THC, and it should be classified federally as a Schedule I substance under the Controlled Substances Act like Delta-9 THC or marijuana. Congress clearly did not intend to legalize Delta-8 and has not acted to legalize Delta-9 THC or marijuana; thus, it should act to treat Delta-8 and Delta-9 the same.

Given the widespread usage and availability of Delta-8, it would be logistically difficult to federally ban it or cannabinoids more generally at this point, and to attempt to do so would not be in consumers' best interest. States have already created an extremely fractured cannabis regulatory environment, and it is entirely possible that some states may pass laws that keep Delta-8 or other types of cannabinoids legal in their borders if the federal government moves to ban them. This would make the cannabis and cannabinoid market even more unwieldy for companies to comply with regulations across markets and dangerous for consumers in states that may enact unsatisfactory safety regulations or none at all. When the FDA was established, it created national standards for food and drugs so exactly this problem does not exist. A patchwork of state regulations, some strong while some weak, hurts the market and the consumer.

In states with legal recreational marijuana laws that have not banned Delta-8 THC, federally banning it may not do anything to prevent Delta-8 from remaining totally unregulated on gas station shelves. Conservative state or local governments may choose not to enforce the federal law and ignore regulating the popular products in order to have the best of both worlds. Continuing to ignore Delta-8 allows conservative politicians to avoid the political consequences of advancing what is perceived as politically liberal or progressive comprehensive cannabis legalization, while at the same time not angering their constituents who desire to easily purchase cannabis products and use Delta-8 instead of illegal marijuana. Even if the federal government attempted to close the Delta-8 loophole, a more tailored definition of hemp designed to exclude Delta-8 from legality but keep hemp and CBD legal would likely miss capturing new cannabinoids hitting the market like Delta-10 or Delta-O THC.<sup>128</sup>

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127. Hemp Access and Consumer Safety Act, S. 1698, 117th Cong. (2021).

128. Levenson, *supra* note 105; Peter Grinspoon, *Beyond CBD: Here come the other*

Additionally, given the general popularity of general cannabis legalization, why would federal politicians even want to push back on the legality of Delta-8?<sup>129</sup> There is promising medical research emerging in part due to greater legal ability to conduct cannabinoids research. Early studies have indicated that compounds in cannabis like THCV and CBN may help patients manage diabetes, weight loss, and ADHD.<sup>130</sup>

The FDA can very easily act to uniformly regulate cannabinoid markets and products across the United States. This will protect consumers. As demonstrated earlier, children are in fact getting sick from accidentally consuming Delta-8. The FDA can take several steps to prevent this from happening, including ensuring that Delta-8 is not sold in candies or sweets that are enticing to children. The FDA can also take steps to mandate childproof packaging on all Delta-8 products.

With FDA regulation, adulterated and mislabeled Delta-8 and other cannabinoid products could be a thing of the past, and consumers would be able to make informed decisions on what and how much of the compounds they will consume. The dangerous unsubstantiated medicinal and therapeutic claims featured in the marketing of many Delta-8 and CBD products can be curbed by the FDA taking regulatory responsibility of the market, saving consumers money, and protecting them from being duped into not seeking proper treatment for their ailments. Ultimately, if Delta-8 and other cannabinoids are to remain in the market, the FDA must act to protect consumers.

## CONCLUSION

To protect consumers and the promise of hemp product markets, the FDA needs to begin to regulate Delta-8 THC and other similar substances. This is in part due to the increasing health and safety issues that an entirely unregulated Delta-8 THC market poses to the American people. It is

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*cannabinoids, but where's the evidence?*, HARV. HEALTH BLOG (Sept. 26, 2022), <https://www.health.harvard.edu/blog/beyond-cbd-here-come-the-other-cannabinoids-but-wheres-the-evidence-2021032322190> [https://perma.cc/YX8A-EQAE].

129. Ted Van Green, *Americans overwhelmingly say marijuana should be legal for recreational or medical use*, PEW RSCH. CTR. (Nov. 22, 2022), <https://www.pewresearch.org/fact-tank/2021/04/16/americans-overwhelmingly-say-marijuana-should-be-legal-for-recreational-or-medical-use/> [https://perma.cc/JWE2-F69X].

130. Grinspoon, *supra* note 128.

unlikely that the greyness of the legality of Delta-8 THC will be resolved without congressional action mandating the FDA to regulate Delta-8 and other similar substances.

Many states have begun to take matters into their own hands and have started to regulate Delta-8 THC in a similar way to their other state legalized forms of cannabis, or banned it entirely.<sup>131</sup> However, the regulatory confusion that we are in now stems from the language legalizing hemp in the 2018 Farm Bill that was not drafted in a way to reflect the extremely complicated chemical nature of the cannabis plant.

Even though passage of the 2018 Farm Bill has sown regulatory confusion, it marked a dramatic change in cannabis regulation in the United States and has ushered in a new era of regulation similar to the country's historical approach to the cannabis plant prior to the passage of the Controlled Substances Act in the 1970's and the Marihuana Tax Act of the 1930's. That system did not include total federal prohibition, but instead consisted of a complicated patchwork of federal, state, and local regulations.

With the current proliferation of Delta-8 and CBD products claiming to be "cures-all's," it is time for the FDA to step in as it did in the past to protect American consumers across the country from these modern patent drugs. However, the FDA should learn from the federal government's past mistakes in the cannabis regulation space. These lessons must not initiate a new age of cannabis prohibition, but instead help foster a system that protects consumers by keeping cannabis products safe while still harassing their benefits.

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131. In July of 2021, the state legislature of Oregon became a leader in the cannabinoid regulation space when it passed, and Governor Kate Brown signed into law a new regulation scheme that essentially regulates all "adult use cannabinoids" in the same system. Both Delta-9 and Delta-8 products, as well as foreseeable future novel cannabinoids would be regulated to allow the public to safely use the product. Nathalie Bougenies, *Oregon's New "THC in Milligrams" Limit*, CANNA L. BLOG (July 29, 2021), <https://harrisbricken.com/cannalawblog/oregons-new-thc-in-milligrams-limit/> [<https://perma.cc/U6NM-XH5G>].